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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,865	10/16/2003	Walter Schubert	S159 1030.1	7435

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WOMBLE CARLYLE SANDRIDGE & RICE
P.O. Box 7037
Atlanta, GA 30357-0037

EXAMINER

BASS, DIRK R

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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07/15/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/686,865	Applicant(s) SCHUBERT, WALTER	
	Examiner DIRK BASS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants response filed April 29, 2010 is acknowledged. Claims 11-20 are withdrawn from consideration. Claims 1-10 and 21 are pending and further considered on the merits.

Response to Amendment

2. In response to applicant's amendment, the examiner maintains the grounds of rejection set forth in the office action dated November 2, 2009.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1-3, 5-7, 10, and 21** are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Blumenfield et al., US 6300124 (Blumenfield, IDS).

Regarding claims 1-3 and 21, Blumenfield discloses a method for preparing biological samples (see "histochemical section", col. 14, l. 17-30) for analysis comprising:

- a. Placing the biological sample on a two-dimensional support (col. 14, l. 17-18 and col. 20, l. 60-62);
- b. Air drying the biological sample (col. 14, l. 17-20 and col. 20, l. 60-62);
- c. Applying protein-precipitating or denaturing first solution L1 to the biological sample on the support (see "PCR buffer containing the missing reagents", col. 21, l. 1-4 and "PCR reagent mixture lacks at least one reagent, such as enzyme", col. 20, l. 65-66) at a first temperature T1 (inherently disclosed) for a first time period Z1 (inherently disclosed);
- d. Applying a protein-precipitating or denaturing solution L2 to the biological sample on the support (see "100% ethanol", col. 21, l. 15-17) at a second temperature T2 for a predetermined second time period Z2 on the support, with

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T2 being lower than T1 (inherently disclosed) and Z2 being longer, equal to, or shorter than Z1 (inherently disclosed); and

e. Drying the sample on the support (see "slides are air dried", col. 21, l. 15-16).

Blumenfield further discloses a method wherein said biological sample is a cell or tissue sample (see "histochemical section", col. 14, l. 17-30) (Claim 5), said solution L2 is an organic solvent (see "100% Ethanol", col. 21, l. 15-17) (Claims 6-7), and after performing the method steps defined above, subjecting said biological samples to a nucleic acid determination method (col. 21, l. 21-58) (Claim 10).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Blumenfield et al. in view of Cech et al., USPA 2003/0096344 (Cech).

Regarding claim 4, Blumenfield fails to explicitly disclose a method wherein a biological sample is frozen.

Cech teaches that it is desirable to freeze a biological sample for later analysis (§ 0363).

At the time of invention, it would have been obvious to one skilled in the art to add the freezing step of Cech with the method of Blumenfield in order to preserve or save the biological sample for later use.

8. **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over Blumenfield et al.

Regarding claim 9, Blumenfield discloses a method wherein T1 is about 80°C (col. 21, l. 1).

While Blumenfield fails to explicitly disclose a method where the temperature is within the claimed range, it would have been obvious to one skilled in the art at the time the invention was made to have T1 fall within the claimed range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (MPEP 2144.05, Section II, Part A).

Response to Arguments

9. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

10. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1797

/DRB/
Dirk R. Bass